SEP 1 0 2003

K031287

Steri-Drape™ Fabric Drape
Summary of Safety and Effectiveness

General Information

Manufacturer:	3M Health Care 3M Center St. Paul, MN 55144-1000 (651) 733-1110
Regulatory Contact:	Scott Sardeson Sr. Regulatory Affairs Associate
Date:	March 21, 2003
Proprietary Name:	Steri-Drape™ Fabric Surgical Drape
Common Name:	Sterile and Non-Sterile Surgical Drape
Predicate Device:	Steri-Drape™ Fabric Surgical Drapes (Class II, KKX)

Device Description

The Steri-Drape™ Fabric Drapes described in this submission are one-piece, single use disposable sheets designed to provide an absorbent sterile barrier during surgical procedures. The drapes cover the patient and are made of an absorbent nonwoven fabric backed with a protective film that stops fluid strike-through.

Steri-Drape™ Fabric Drapes are provided in various sizes and shapes to meet the surgeon's needs. In general, the surgeon delineates the proposed field of surgery and charges the nursing team with the responsibility of draping the patient using different types of drapes.

Indication for Use

3M Steri-Drape™ Surgical Fabric Drapes are used to create a sterile field for a surgical procedure. They are provided sterile using ethylene oxide or gamma irradiation, and intended for external use only.

3M Steri-Drape™ non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide processing.

Substantial Equivalence

The Steri-Drape™ fabric drapes described in this submission are substantially equivalent to the currently marketed Steri-Drape™ fabric drapes. These drapes have the same intended use as the currently marketed Steri-Drape™ Fabric Drapes.

Description of Testing

In addition to performance testing in accordance with industry recognized test methods, these drapes were tested for biocompatibility using

cytotoxicity, primary skin irritation tests, and sensitization testing. All testing indicated that the drapes described above were biocompatible and acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2003

Mr. Scott S. Sardeson
Senior Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
Street Paul, Minnesota 55144-1000

Re: K031287
Trade/Device Name: Steri- Drape Surgical Drapes
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: July 24, 2003
Received: July 28, 2003

Dear Mr. Sardeson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031287

Device Name: 3M Steri-Drape™ Surgical Fabric Drapes

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Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031287

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)